



# Research on Synthesis and Evaluation of Nanoparticles of Antidiabetics Drug

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## ABSTRACT

The present study focuses on the synthesis and evaluation of nanoparticles containing the antidiabetic drug voglibose to overcome its limitations of low oral bioavailability and frequent dosing. Voglibose-loaded nanoparticles were prepared using a solvent evaporation method employing biocompatible polymers such as PLGA and chitosan. The nanoparticles were characterized by particle size analysis, zeta potential measurement, encapsulation efficiency, and morphological studies using scanning electron microscopy (SEM). The optimized nanoparticles exhibited a particle size of approximately 180–200 nm, with high drug encapsulation efficiency and a negative zeta potential indicating good stability. In vitro release studies demonstrated a sustained drug release profile, suggesting potential for prolonged therapeutic action. Furthermore, preliminary in vivo studies in diabetic animal models revealed enhanced antidiabetic activity compared to pure voglibose. The results indicate that nanoparticle-based delivery of voglibose could be a promising strategy for improved management of type 2 diabetes mellitus.

**Keywords:** Voglibose, Nanoparticles, Antidiabetic drug delivery, Sustained release, PLGA, Chitosan, Bioavailability enhancement, Type 2 diabetes mellitus.

## INTRODUCTION

Nanotechnology is a multidisciplinary field that involves the design, synthesis, and application of materials at the nanoscale, typically between 1 and 100 nanometers. At this scale, materials often exhibit unique physical, chemical, and biological properties that differ significantly from their bulk counterparts. These novel properties open up numerous possibilities for innovative applications across various industries, particularly in medicine. Nanomedicine, a branch of nanotechnology, refers to the use of nanoscale materials and techniques for the diagnosis, treatment, monitoring, and control of biological systems. It offers significant advantages over traditional medicine, including improved drug solubility, enhanced bioavailability, targeted drug delivery, controlled release, and reduced side effects. By enabling drugs to be delivered directly to diseased cells or tissues with high precision, nanomedicine aims to increase therapeutic efficacy while minimizing systemic toxicity. In the context of chronic diseases such as diabetes mellitus, nanotechnology-based drug delivery systems have shown promise in overcoming challenges associated with conventional therapies, such as poor drug stability, rapid metabolism, and the need for frequent dosing. Nanoparticles, liposomes, dendrimers, and nanoemulsions are among the most explored carriers in nanomedicine. Their ability to encapsulate both hydrophilic and hydrophobic drugs makes them particularly valuable in enhancing the pharmacokinetic and pharmacodynamic profiles of therapeutic agents. This study explores the synthesis and evaluation of voglibose-loaded nanoparticles, aiming to improve its clinical performance by leveraging the principles of nanotechnology and nanomedicine.

Diabetes is a disease characterized mainly by hyperglycemia, which increases the risk of microvascular damage (retinopathy, nephropathy and neuropathy). It is associated with reduced life expectancy, significant morbidity from certain diabetes-related micro vascular complications, increased risk of macrovascular complications (coronary heart disease, stroke and peripheral vascular disease), and diminished quality of life. According to the largest global diabetes prevalence study ever, the global cost of diabetes is now \$825 billion annually

**Type I Diabetes Mellitus:** Type I Diabetes Mellitus, previously known as insulin dependent diabetes or juvenile onset diabetes is an autoimmune disorder that involves the destruction of the B cells by activated CD4<sup>+</sup> and CD8<sup>+</sup> T cells and macrophages infiltrating the pancreatic islets. " The onset of Type 1 diabetes mellitus usually occurs in childhood and early adulthood (<35 years). Genetic as well as environmental factors are known to contribute to the susceptibility to this diabetes. Genetic studies have shown that the HLA (human leucocyte antigen) gene on chromosome 6 is closely associated with Type 1 diabetes mellitus. HLA proteins are located on the surface of cells that help the immune system distinguish between the body's normal cells and foreign infectious and non-infectious substances. In Type 1 diabetes mellitus, an

abnormality in the HLA proteins leads to an autoimmune reaction against the B cells. another gene in the HLA vicinity plays an important role in Type 1 Diabetes Mellitus. Evidence exists suggesting that certain viruses may be responsible in triggering Type 1 diabetes mellitus. Some patients sustain another form of Type 1 diabetes mellitus, called idiopathic diabetes that does not involve autoimmunity. It is less common than the autoimmune Type 1 diabetes mellitus, and is found in African and Asian populations. The etiology and pathogenesis are not well understood, but the patients lack insulin production and are prone to ketoacidosis in the absence of antibodies to  $\beta$  cells. Fulminant type 1 Diabetes Mellitus is another subtype of Type 1 diabetes mellitus in which extremely rapid and almost complete destruction of  $\beta$  cells occurs.

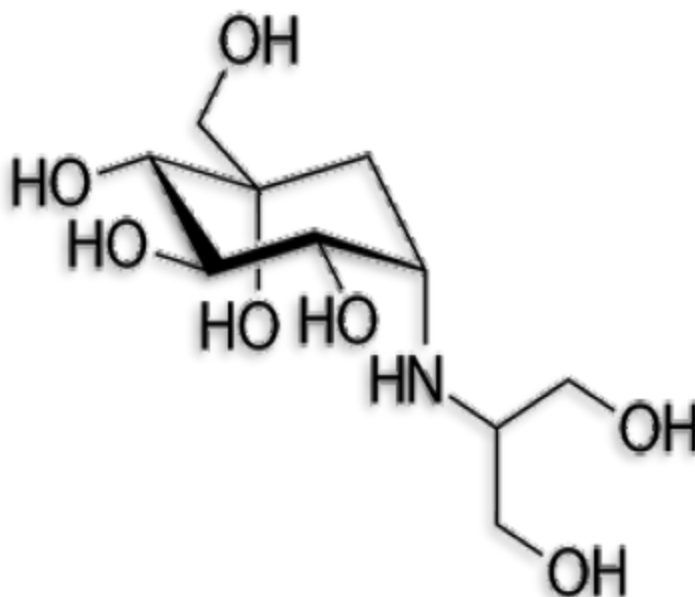
**Type 2 Diabetes Mellitus:** Type 2 diabetes mellitus is characterised by insufficient synthesis of insulin and its secretion, secondary to insulin resistance. It is normally diagnosed after the fourth decade of life, and accounts for

approximately 90% of all diabetes worldwide. The incidence and prevalence of type 2 diabetes mellitus are found to increase with age. Type 2 diabetes mellitus is divided into two subgroups, diabetes with obesity and without obesity. The obese Type 2 diabetes mellitus patients usually develop resistance to endogenous insulin due to alterations in cell receptors, and this is associated with distribution of abdominal fat. In non-obese Type 2 diabetes mellitus there is some insulin resistance at the post receptor levels in addition to a deficiency in insulin production and release. Since obesity and aberration of metabolic factors are central to the incidence of Type 2 diabetes mellitus, the notable changes in diet and lifestyle in developing countries support the highest prevalence of diabetes occurring in these countries.

**Regulation of Blood Glucose:** Blood glucose regulation is based on negative feedback and works through the release of insulin and glucagon. When glucose levels in blood are high, the  $\beta$  cells of the islet of Langerhans in the pancreas are triggered to release insulin, a 51-amino acid polypeptide that consists of two chains (A and B) connected by a disulfide bridge. Insulin is synthesised from pro-insulin by the pro-hormone convertases (PC 1 and PC2), and exo-protease carboxy peptidase. The action of these enzymes generates insulin and C-peptide. Insulin binds to the tyrosine kinase insulin receptor which is made up of two  $\alpha$  subunits (extracellular) and two  $\beta$  subunits (intra membrane) linked by disulfide bonds. The binding of insulin to the  $\beta$  subunit of tyrosine kinase insulin receptor promotes auto phosphorylation of the  $\beta$  subunit. Insulin signals the liver to turn excess glucose into glycogen for storage; it also triggers other body cells (fat/muscle cells) to take up more glucose by moving the glucose transporter (GLUT4) to the cell surface. This helps to bring the circulating glucose concentrations to normal levels. When the glucose concentration in the blood is low, the  $\alpha$  cells of the pancreas are stimulated to release glucagon. Glucagon signals the liver to convert stored glycogen into glucose, which is released into the blood to achieve homeostasis. In diabetes, there is an aberration either in the synthesis or secretion of insulin as seen in Type 1 diabetes mellitus and stenosis in the pancreatic duct, or the development of resistance to insulin or its subnormal production as in the case of Type 2 diabetes and certain secondary diabetes.

## DRUG AND EXCIPIENT PROFILE:

**Drug profile: Voglibose**





**IUPAC name:**5-(1,3-dihydroxypropan-2-ylamino)-1-(hydroxymethyl)cyclohexane-1,2,3,4-tetraol

**Molecular Formula:** C<sub>10</sub>H<sub>21</sub>O<sub>7</sub>, **Molecular Weight:** 267.278gmol<sup>-1</sup>, **Melting point:** 161-166°C

**Category:** It is used as an Anti-diabetic. It is used mainly to treat diabetic mellitus by lowering post-prandial blood glucose level.

**Storage:** It should be stored in a well closed container and protected from light.

**Half Life:** Half life of voglibose 4 hours.

**Brand Name:**VOBOSE,VIGISA,VOGLOBOZ,CONOVOG-M3

Sr. No	Chemicals	Sr. No	Instruments
1.	Voglibose (drug)	1.	<b>Electronic Balance:</b> Used for accurate weighing of voglibose, HPMC, and other formulation components.
2.	HPMC (polymer — Hydroxypropyl Methylcellulose)	2.	<b>UV-Visible Spectrophotometer:</b> Used to determine drug concentration for calibration curves, drug loading, and entrapment efficiency analysis.
3.	Acetone (organic solvent)	3.	<b>Magnetic Stirrer:</b> Employed for continuous stirring during the emulsification and solvent evaporation process.
4.	Methanol (co-solvent)	4.	<b>Sonicator:</b> Used to enhance emulsification and reduce droplet size during nanoparticle formation.
5.	Distilled Water (aqueous phase)	5.	<b>Magnetic Shaking Incubator:</b> Provided controlled temperature and agitation for solvent evaporation and stabilization of the emulsion.
6.	Polysorbate 20 (Tween 20) (surfactant/stabilizer)	6.	<b>Centrifuge:</b> Used to collect nanoparticles by separating them from the aqueous phase after formulation.
		7.	<b>Particle Size Analyzer (e.g., DLS Analyzer):</b> Used to measure the average particle size and size distribution (polydispersity index, PDI) of the nanoparticles.
		8.	<b>Melting Point Apparatus:</b> Used to determine the melting point of voglibose for identity confirmation and purity check.
		9.	<b>Fourier Transform Infrared Spectroscopy (FTIR):</b> Used for structural analysis to confirm drug-polymer interactions and to verify the compatibility of voglibose with HPMC.

**Mechanism of action:** Alpha-glucosidase inhibitors are saccharides that act as competitive inhibitors of enzymes needed to digest carbohydrates: specifically alpha- glucosidase enzymes in the brush border of the small intestines. The membrane-bound intestinal alpha-glucosidases hydrolyze oligosaccharides, trisaccharides, and disaccharides to glucose and other monosaccharides in the small intestine. Acarbose also blocks pancreatic alpha- amylase in addition to inhibiting membrane-



bound alpha-glucosidases. Pancreatic alpha-amylase hydrolyzes complex starches to oligosaccharides in the lumen of the small intestine. Inhibition of these enzyme systems reduces the rate of digestion of complex carbohydrates. Less glucose is absorbed because the carbohydrates are not broken down into glucose molecules. In diabetic patients, the short-term effect of these drugs therapies is to decrease current blood glucose levels: the long term effect is a small reduction in hemoglobin-A1c level.

**Pharmacodynamics:** Voglibose, an alpha-glucosidase inhibitor, is a synthetic compound with potent and enduring therapeutic efficacies against disorders of sensory, motor and autonomic nerve systems due to diabetes mellitus. The drug was approved in Japan in 1994 for the treatment of diabetes, and it is under further investigation by Takeda for the treatment of impaired glucose tolerance. Alpha-glucosidase inhibitors are oral anti-diabetic drugs used for diabetes mellitus type 2 that work by preventing the digestion of complex carbohydrates (such as starch). Complex carbohydrates are normally converted into simple sugars (monosaccharides) which can be absorbed through the intestine. Hence, alpha-glucosidase inhibitors reduce the impact of complex carbohydrates on blood sugar.

**Dosage and Route of Administration:** Voglibose is given by mouth in doses of 0.3 mg one to three times daily.

**Adverse Effect:** Diarrhoea, Abdominal pain, Dizziness, Nausea, Flatulence, skin rash, Abnormal liver pain, Digestive disorder, Loss of appetite.

## MATERIALS AND METHODS

### Method:

**Solvent evaporation Method:** The solvent evaporation method is one of the most widely used techniques for the preparation of polymeric nanoparticles, especially for encapsulating poorly soluble or sensitive drugs. This method involves dissolving both the drug and the polymer in an organic solvent that is immiscible with water, followed by emulsification into an aqueous phase containing a stabilizer or surfactant. Upon evaporation of the organic solvent, the polymer precipitates, forming solid nanoparticles that encapsulate the drug.

### Steps Involved:

1. **Dissolution:** The drug (e.g., voglibose) and a biodegradable polymer (e.g., PLGA, chitosan, or PCL) are dissolved in a suitable volatile organic solvent such as dichloromethane, chloroform, or ethyl acetate.
2. **Emulsification:** The organic phase (drug + polymer solution) is slowly added to an aqueous phase containing a stabilizer like polyvinyl alcohol (PVA) under high-speed homogenization or ultrasonication to form an oil-in-water (O/W) emulsion.
3. **Solvent Evaporation:** The emulsion is stirred at room temperature or under reduced pressure to evaporate the organic solvent. As the solvent evaporates, the polymer hardens into nanoparticles entrapping the drug.
4. **Collection and Washing:** The nanoparticles are collected by centrifugation, washed several times with distilled water to remove any residual stabilizer or solvent, and then lyophilized (freeze-dried) for storage.

**Polymer:** The choice of polymer depends on the desired drug release profile, biocompatibility, and biodegradability. Commonly used polymers include:

- ✓ **PLGA** (poly(lactic-co-glycolic acid)) – FDA-approved, excellent for sustained release.
- ✓ **Chitosan** – Natural, mucoadhesive, and enhances drug absorption.
- ✓ **PCL** (polycaprolactone) – Biodegradable and suitable for very slow release profiles.

**Preformulation studies:** Every drug has inherent physical and chemical properties which were considered before pharmaceutical formulation being developed. These different physical and chemical properties provide the basis combination of drug API with various pharmaceutical ingredients and excipients. Preformulation studies strengthen the scientific basis of the guidelines, provide regulatory relief and save resources in the drug formulation, development and evaluation process, boost public health standards, enhance product quality in dosage form manufacturing. These studies will concentrate on the new compound's physicochemical properties that could influence the performance of drugs and the production of an effective dosage form.

**Solubility Study:** Solubility of drug is defined as the amount of solute (drug) that dissolves into a given solvent (solution) to obtain saturated solution of drug at constant temperature and constant pressure. Solubility is an integral parameter of preformulation which has been studied extensively. This focuses on the drug-solvent mechanism which can occur during the delivery of drugs. Such knowledge is important for the formulator, as it gives the information about the selection of best solvent medium for drug substance, recognize and overcome the challenges that occur in the formulation process of pharmaceutical solutions. Solubility of Voglibose Citrate was tested in various solvents.



**Melting point determination:** Melting point determination of Voglibose was carried out by using melting point apparatus. Readings were recorded in triplicates.

**Analytical Profile:**

**A. Determination of Voglibose analytical wavelength:**

**Selection of solvent:** The solubility of Voglibose was determined in variety of solvents as per Indian Pharmacopoeia. Solubility was carried out in different polar and non-polar solvents. From the solubility data Methanol was selected as solvent for the analysis of Voglibose.

**Preparation of standard stock solution of Voglibose:** 100 mg quantity of Voglibose weighed accurately and transferred in 100 ml volumetric flask. Sufficient quantity of methanol is added to the flask to dissolve the drug. Solution is sonicated for 15 min and then diluted up to 100 ml with same solvent, so as to obtain concentration of 100 µg/ml. pipette out 1ml from the above 100 µg/ml stock solution and added to 10 ml volumetric flask an diluted up to 10 ml with methanol to get concentration of 10 µg/ml.

**Selection of wavelength / determination of lambda max:** The above 10 µg/ml solution were scanned in UV range 400 to 200 nm in 10 mm quartz cell against blank solution separately using UV visible spectrophotometer. From the obtained spectra, lambda max for Voglibose is determined.

**B. Construction of standard calibration curve:** Five working standard solutions are prepared by pipette out the from standard stock solutions of Voglibose. From standard stock solution 1.0 ml, 2.0 ml, 3.0 ml, 4.0ml and 5.0ml were pipette out in 10 ml volumetric flask and diluted up to 10 ml by solvent 0.1M HCL to get working solutions of concentration 10, 20, 30, 40 and 50 µg/ml respectively. These series of different concentrations of Voglibose were scanned at 281 nm using a UV spectrophotometer (Jasco V-630) and the absorbance of all dilutions was recorded. The standard calibration curve was constructed by plotting concentrations on the x-axis versus absorbances on the y-axis over the range of 10 to 50 µg/ml.

**Selection of polymer for nanoparticles formulation: HPMC:** HPMC is selected as a hydrophilic polymer to prepare polymeric nanoparticle formulation. HPMC is widely used in oral, ophthalmic, and topical controlled-release dosage forms because of its non-toxic nature. Its capacity to accommodate the high level of drug loading and its non-pH dependence.

**Preparation of Polymeric Nanoparticles:**

**Nanoparticles were prepared according to the Solvent evaporation method.:**

Voglibose nanoparticles were prepared using the solvent evaporation method. Initially, voglibose (drug) and hydroxypropyl methylcellulose (HPMC, polymer) were accurately weighed and dissolved in a mixture of methanol and acetone to form the organic phase. This organic solution was then added dropwise using a syringe into distilled water containing polysorbate 20 (Tween 20) under continuous magnetic stirring to form an oil-in-water (O/W) emulsion. The resulting emulsion was stirred continuously for 24 hours to facilitate the evaporation of methanol and acetone, leading to the formation of a nanoparticulate suspension. The suspension was then subjected to centrifugation at 1500 rpm at 4°C for 30 minutes. After centrifugation, the supernatant was discarded, and the collected nanoparticle precipitate was washed three times with distilled water to remove any unbound surfactant and impurities. Finally, the washed nanoparticles were dried in a hot air oven at 60°C for 1 to 2 hours to obtain dry voglibose nanoparticles. The prepared batches were characterized for loading efficiency, particle size, drug content, surface morphology using scanning electron microscopy (SEM), and evaluated for in vivo antidiabetic activity.

**Table : Ingredient for Nanoparticles Preparation**

Sr No	Ingredient	Batch					
		F1 (1:1)	F2 (1:2)	F3 (1:3)	F4 (1:4)	F5 (1:5)	F6 (1:6)
1	Voglibose (mg)	100	100	100	100	100	100
2	HPMC (mg)	100	200	300	400	500	600
3	Methanol+ Acetone	80 ml	80 ml	100 ml	80 ml	100 ml	80 ml





4	Distilled Water (ml)	20 ml	20 ml	20 ml	20 ml	20 ml	20 ml
5	(Tween 20) Surfactant and Stabilizer	1ml	1ml	1ml	1ml	1ml	1ml

**Characterization of polymeric Nanoparticles:** Prepared Voglibose nanoparticles were characterized by the following evaluation parameter:

**1.FT-IR spectroscopy study:** Infrared spectra of pure water-free Voglibose powder samples are recorded by using an FT-IR spectrophotometer (Jasco IR 4500) by suitably diluting with potassium bromide (KBr) at ambient temperature.

**2.Particle size analysis:** Particle size analysis of Voglibose polymeric nanoparticles was determined using Microtrac nano sizer.

**3. Drug content:** The total drug content in nanoparticles is quantified by Spectrophotometric analysis. 1 mg equivalent of Voglibose polymeric nanoparticle is dissolved in 1 ml of Methanol and the volume is made up to 100 ml to make 10 µg/ml concentration and the absorbance is measured at 281 nm ( $\lambda_{max}$ ) using UV spectrophotometer.

The calculation is performed as follows:

$$\text{Vol. Total}$$

$$\text{Total drug content} = \frac{\text{Vol. Aliquot}}{\text{Vol. Total}} \times \text{Drug amount in aliquot}$$

**6. Entrapment Efficiency:** For the determination of drug entrapment, the amount of drug present in the clear supernatant after centrifugation was determined (w) by UV spectrophotometer at 281 nm. A standard calibration curve of the drug was plotted for this purpose. The amount of drug in the supernatant was then subtracted from the total amount of drug added during the preparation (W). Effectively, (W-w) will give the amount of drug entrapped in the particles. Then percentage entrapment of a drug was calculated according to the Equation:

$$\text{Drug Entrapment (W-w/W) } \times 100$$

**7. Loading efficiency:** The drug content in the preparation was determined by extracting the drug from the nanoparticles with methanol. In this method, the nanoparticles (50 mg) were stirred in 50 ml of methanol until dissolved; it was filtered through a Millipore filter and the drug content was determined, after suitable dilution, at 281 nm by UV spectrophotometry. The loading efficiency (L) of the nanoparticles was calculated according to the Equation:

$$L(\%) = \left( \frac{Q_n}{W_n} \right) \times 100$$

Where  $W_n$  is the weight of the nanoparticles and  $Q_n$  is the amount of drug present in the nanoparticles.

**8. Zeta potential analysis:** Zeta potential is a measure of surface charge. The Zeta potential of prepared polymeric nanoparticles was performed for estimation of the stability of Voglibose polymeric nanoparticles. Zeta potential measurement was performed using Microtrac Instrument.

**9. In-vivo study:** 7mg/kg voglibose API ,0.3 ml nanoparticles ,0.3 mg marketed formulation were administered to the 3 Wister rat separately by per oral route of administration . Voglibose API has  $C_{max}$  of 4 hours hence the blood withdrawal was done after the two hours of administration. Blood withdrawal was done by retro orbital . Around 2 ml of blood was withdraw from each rat and centrifugation was done at 3000 rpm for 10 min to separate . After separation to the 9 ml of each standard solution (20 ppm ) 1 ml plasma was added and absorbance was taken at 281 nm.

## RESULT AND DISCUSSION

### Physical characteristics:

Voglibose was checked for its colour, odour, and texture. It is a white to an off-white powder having slightly bitter taste.

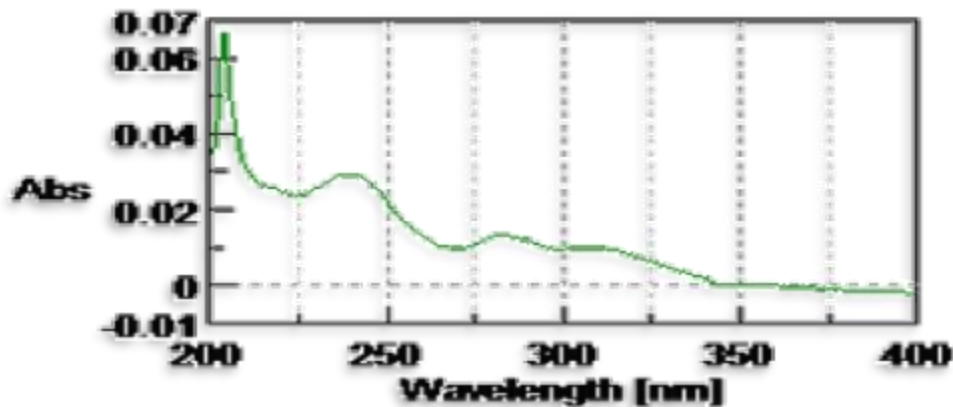
### Solubility:

A solubility test for voglibose was carried out in different solvents.

Sr.No	Solubility	Solvent
1	Freely soluble	Methanol, Ethanol, Acetone, Dimethyl formamide
2	Sparingly soluble	Dichloromethane, phosphate buffer
3	Slightly soluble	Diethyl ether
4	Very slightly soluble	Distilled water.
	Melting point (standard M.P.- 161°C-166°C)	163°C

**Table : Solubility and Melting point of Voglibose**

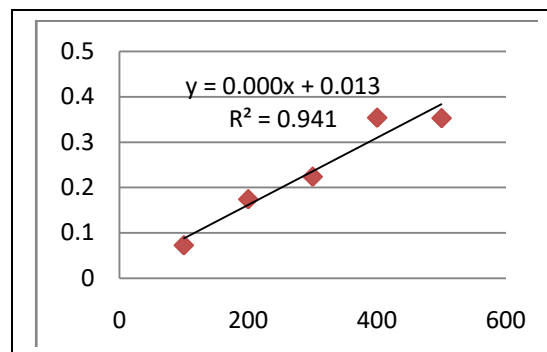
**Analytical Profile: Determination of Voglibose analytical wavelength:** The prepared aliquots were scanned in the UV range 400 to 200 nm in 10 mm quartz cell against blank solution separately using UV visible spectrophotometer. The lambda max of Voglibose in Methanol was found to be 281 nm.



**Fig - UV Spectra of Voglibose**

**Calibration curve for Voglibose:** The series of different concentrations of Voglibose was scanned at 281 nm using UV spectrophotometer (Jasco V-630) and absorbance of all dilutions was recorded. The standard calibration curve for Voglibose in Methanol was constructed by plotting concentrations on x-axis versus absorbances on y-axis over the range of 10 to 50 µg/ml.

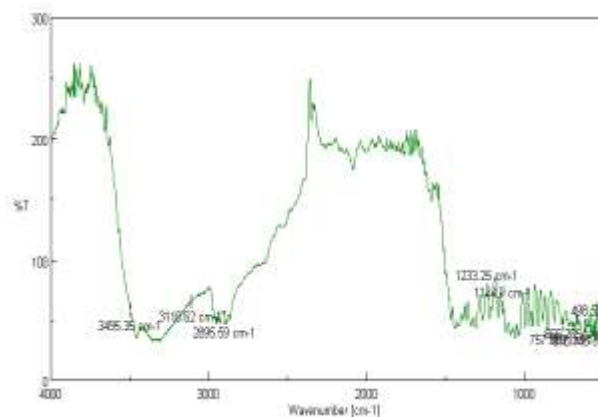
Sr.No	Concentration (µg/ml)	Absorbance At 282nm
1	0	0
2	10	0.0729
3	20	0.1743
4	30	0.224
5	40	0.3539
4	50	0.3529



Sr.No	Parameter	Values
1.	Absorbance maximum (lambda max)	281 nm
2.	Regression Coefficient ( $R^2$ )	0.9412
3.	Slope	0.0007
4.	Intercept	0.0137
5.	Regression equation	$Y = 0.0007 + 0.0137$

**FT-IR Spectroscopy Analysis:** Fourier Transform Infrared (FT-IR) spectra of the sample were obtained using FTLR jasco spectrometer by KBr disc method. The spectrum were recorded for the pure drug, polymer.

Sr.No	Functional group	Standard Frequency ( $\text{Cm}^{-1}$ )	Observed Frequency ( $\text{Cm}^{-1}$ )
1	O-H Stretching	3500-3400	3460.63
2	C-H Stretching	2500-3400	2889.81
3	C-H bending	1870- 1540	1648.84
4	C-O-C Streaching	1450-1350	1440.56
5	O-H bending	1016-917	946.877



As per the FT-IR spectrum, the characteristic peaks of HPMC were not altered.



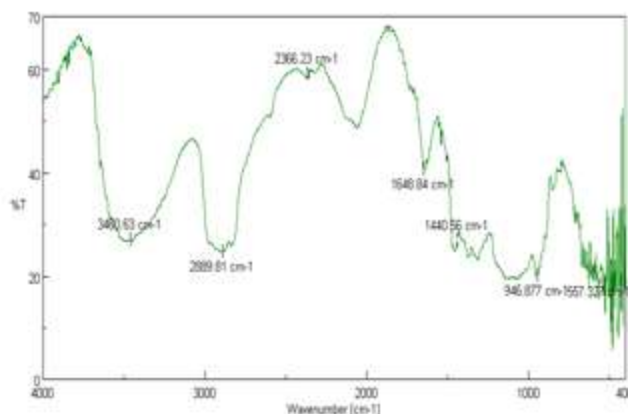


Fig . FT-IR Spectra of HPMC

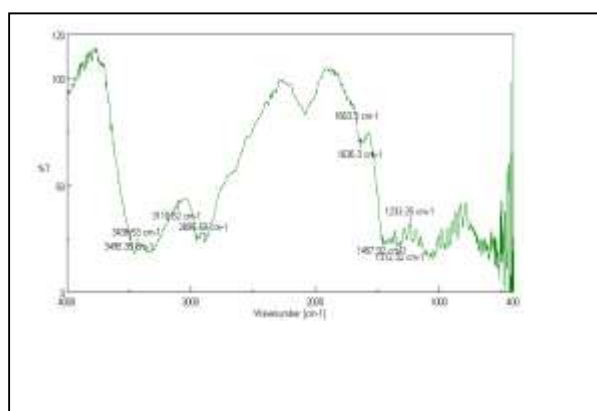


Fig FT-IR Spectra of Mixture of Drug and Polymer.

Table - IR spectra of HPMC

Sr.No	Functional Group	Standard Frequency (cm <sup>-1</sup> )	Observed Frequency (cm <sup>-1</sup> )
1	C-OH Stretching	3900-3100	3495.35
2	O-H Stretching	3500-3400	3436.53
3	C-H Stretching	2500-3400	2895.59
4	C-H bending	1870-1540	1663.3
5	C- N Stretching	1200-1350	1312.32
6	O-H bending	1067-917	946.877

Table - IR spectra of Mixture of drug and Polymer

The FT-IR spectra of pure drug voglibose are reported in figure 8.5 and table 8.6. Characteristic IR absorption peaks of mixture of drug and polymer of C-OH stretch (3495.35cm), O-H Stretch (3436.53), C-H stretch (2895.59cm), C-H bending(1663.3), C-N stretch

(1312.32cm), O-H bending (946.877) were present in the IR spectrum of the of mixture of drug and polymer . The FT-IR spectra of of mixture of drug and polymer indicated that the positions of characteristic peaks of voglibose were not altered

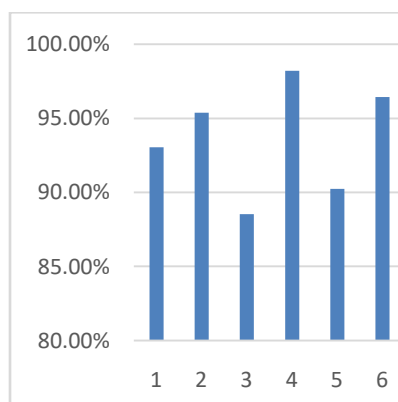
## II. Characterization of Polymeric nanoparticles: The polymeric nanoparticles show the following characteristics:

Sr. No	Batch Code	Drug content (%)	Sr. No	Batch Code	Entrapment Efficiency (%)	Sr. No	Batch Code	Loading Efficiency (%)
1	F1	93.04%	1	F1	83.09%	1	F1	35.10 %
2	F2	95.37%	2	F2	84.51%	2	F2	37.54 %
3	F3	88.54%	3	F3	81.04%	3	F3	34.05%
4	F4	98.2%	4	F4	88.87%	4	F4	40.91%
5	F5	90.24%	5	F5	81.11%	5	F5	29.78%
6	F6	96.44%	6	F6	86.63%	6	F6	38.26%

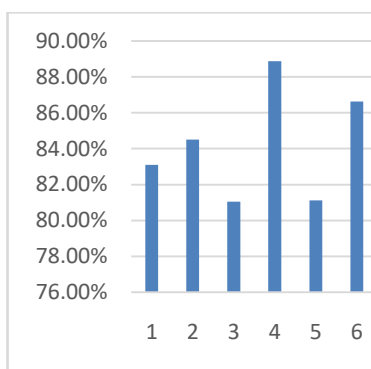
**Table- Drug Content of Polymeric Nanoparticles.**

**Table- Entrapment Efficiency of Polymeric Nanoparticles.**

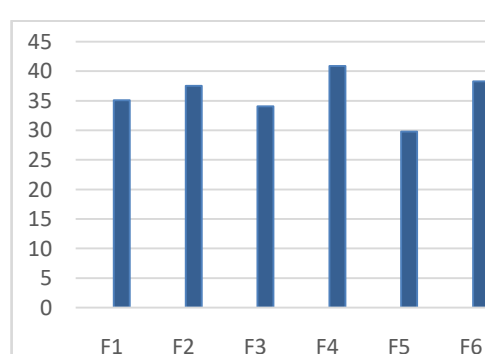
**Table-Loading Efficiency of Polymeric Nanoparticles.**



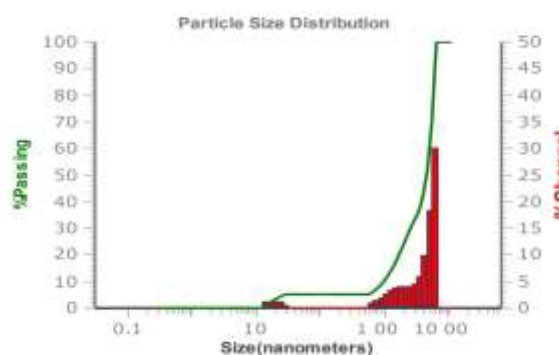
**Fig.- Drug Content in Polymeric Nanoparticles**



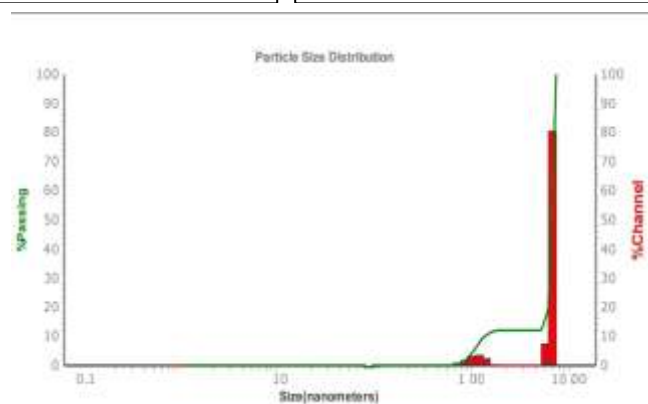
**Fig.- Entrapment Efficiency in Polymeric Nanoparticles.**



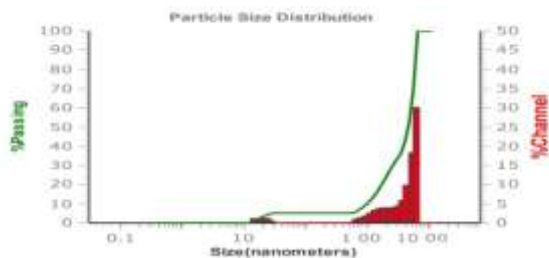
**Fig.- Loading Efficiency in Polymeric Nanoparticles.**



**Fig.-Particle Size of Polymeric Nanoparticles(BatchF4)**



**Fig.- Particle Size of Polymeric Nanoparticles Formulation (Batch F6)**



Measured Data	
Zeta Potential	117.6 mV
Polarity	Negative
	(Automatic)
Mobility	9.19 $\mu\text{m/s/V/cm}$
Conductivity	103 $\mu\text{S/cm}$
Field Strength (Req/Act)	10 / 9.9 kV/m
SOP	
Zeta Run Time	30 sec

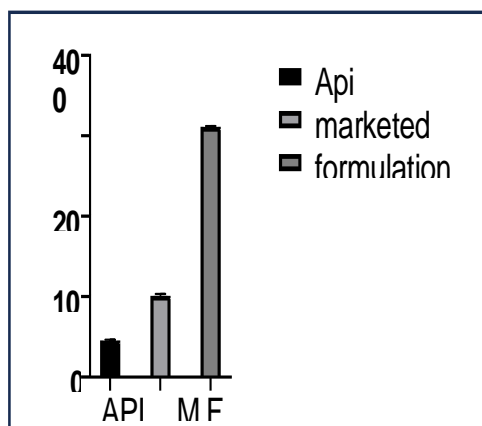
### Scanning Electron Microscopy (SEM):

SEM analyses of the formulated Voglibose polymeric nanoparticles were performed to evaluate the surface morphology of nanoparticles. SEM images showed that the nanoparticles were smooth surface morphology and were spherical in shape. The SEM images of formulation F4 are shown in Figure



**Fig- SEM mage Of Voglibose**

**IN-VIVO STUDY:** The plasma drug concentration versus time profile of Pure drug (API), Voglibose nanoparticles, and Marketed formulation after oral administration. The Voglibose nanoparticles concentration maximum ( $C_{\text{max}}$ ) is higher than the pure drug (API) and marketed formulation. Due to its limited solubility and BCS class II classification, the drug requires a greater dissolving rate via nanoparticles aids in reaching a higher  $C_{\text{max}}$  than an API. The increased bioavailability of the drug was primarily due to two mechanisms. Initially, nano sizing increased surface area while decreasing particle size. Second, there was direct contact between the surfaces as are sultofa decrease in the thickness of the diffusion layer and an increase intheadhesionsurfaceareabetweennanoparticlesandtheintestinalepitheliumof villi. Third, the medication was released right away, increasing its availability at the site of absorption. This is in agreement with the enhanced bioavailability of voglibose nanoparticles than marketed formulation and pure drug (API).



## DISCUSSION

Polymeric Nanoparticles formulation technology is one of the promising techniques that can be used for improving the solubility of such BCS class II and class IV drugs. Voglibose is a antidiabetic drug. It has been used in the treatment of diabetic In Nanoparticles a large variety of substances can be encapsulated. The separticles possess the ability to carry both lipophili can dhydrophilic substances and there by improving the solubility of poorly water-soluble molecules. The high incidence of administration of Voglibose together with its short half-life and poor bioavailability proposed great scope for the proposal of nanoparticulate drug delivery systems. Main objective of this study was to synthesis and evaluate Voglibose loaded polymeric nanoparticles using polymers to increase bioavailability of drug. This formulation reduced the side effects, minimized the dosing frequency and dose.

The present work aimed at synthesizing and evaluating Voglibose loaded polymeric nanoparticles with polymers HPMC using Solvent Evaporation Method. This method was simple and cost effective. Preformulation studies were carried out to find out the solubility of Voglibose. Solubility test gave an idea that Voglibose is very slightly soluble in distilled water but freely soluble in solvents like ethanol, DMSO, acetone, chloroform, etc. UV spectral studies authenticate the spectra obtained with the sample drug matched with standard pure drug. UV spectra gave the maximum absorption peak at 281. The comparison of FTIR spectra of Voglibose, HPMC polymer and physical mixture of Voglibose and polymers confirms that there is no appearance of additional new peaks and disappearance of existing peaks from that of the drug. This indicates that there is no interaction between the drug and polymers used in the study. The different batches of polymeric nanoparticles were synthesized by Solvent evaporation method followed by centrifugation. HPMC used as polymers, while Methanol and acetone were used as solvents and Polysorbate tween 20 as a surfactant for drug and polymer respectively. The amount of drug content in Voglibose loaded polymeric nanoparticles was calculated and all the prepared polymeric nanoparticle formulations were found to possess very high drug content.

The highest drug content was found to be 98.2% of F4 batch. The amount of drug being entrapped in Voglibose loaded polymeric nanoparticles was calculated and all the prepared polymeric nanoparticle formulations were found to possess very high entrapment efficiency. The highest entrapment efficiency was found to be 88.87% of F4 batch. The amount to drug being loaded in Voglibose loaded polymeric nanoparticles was calculated. The highest loading efficiency was found to be 40.91 of F4 batch. Particle size, and zeta potential were determined by Microtrac Zeta sizer. The particle size analysis confirmed that the prepared sample were in then an ometerrange. A verage particle size obtained for the batch F4 was found to be in Nanometer. Zeta potential value of polymeric nanoparticles indicated that the polymeric nanoparticles are stable. Zeta potential value of polymeric nanoparticle formulation F4 was found to be -117.6 mV. Scanning Electron Microscopy (SEM) analysis of the prepared Voglibose loaded polymeric nanoparticles at different magnification showed that the polymeric nanoparticles were smooth surface morphology and spherical shape. The plasma drug concentration versus time profile of Pure drug (API), Voglibose nanoparticles, and Marketed formulation after oral administration. The Voglibose nanoparticles concentration maximum (C<sub>max</sub>) higher than the pure drug (API) and marketed formulation.

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